

Subject: First Generic for Lyrica® Launches

On Friday, July 19, 2019, the “much anticipated” market release of a Food and Drug Administration (FDA) approved generic for Lyrica (pregabalin capsules) was announced. Rising Pharmaceuticals announced the U.S. launch and commercial shipment of the first generic pregabalin capsules, in all eight commercially available strengths (25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg and 300mg).¹

Lyrica is FDA approved for the management of neuropathic pain associated with diabetic peripheral neuropathy, post-herpetic (after shingles) neuralgia, and fibromyalgia. It also carries a label indication for adjunctive therapy of partial onset seizures in adults.² Prescribers in search of alternatives to opioid pain medications have turned increasingly to Lyrica and other medications to manage pain of neuropathic origin.

Specific pricing information for the new generics was unavailable at the time of this publication, but applications for ten additional Lyrica generics have been approved³ and are in progress to market. Increasing competition over time will predictably bring further reductions in price. It should be noted that no generic for Lyrica CR (pregabalin extended release) is presently available, as this formulation was first approved in late 2017 and patent exclusivity is in place through 2026.

The Impact

Lyrica reported U.S. sales of approximately \$5.5 billion for the year ending in March 2019.⁴ As the costliest and most utilized brand medication in the First Script book of business,⁵ the arrival of an approved generic is an important development for injured workers, prescribers, and payers alike. As pricing for this first generic entry becomes clear, and additional generics announce their own introductions, the impact on costs and utilization will become more predictable. First Script will continue to monitor the evolving market conditions around the introduction of generic Lyrica and will continue to provide Smart Prior Authorization (PA) messaging to alert adjusters to new prescriptions for extended release versions of Lyrica.

If you have additional questions, please contact your Account Manager or Account Pharmacist.

References:

1. <https://www.businesswire.com/news/home/20190719005382/en/>
2. https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021446s026_022488s005lbl.pdf
3. <https://www.medscape.com/viewarticle/915877?src=android&devicetype=android&osversion=8.0.0&appversion=6.1.1&src=medscapeapp-android&ref=share>
4. <https://www.biospace.com/article/releases/rising-pharmaceuticals-announces-the-u-s-launch-of-a-generic-version-of-pregabalin-capsules/>
5. Drug Trends Compilation – Coventry, Nov. 18, 2018, https://coventrywcs.com/content/dam/pdf_assets/drug_trends/DrugTrendsSeries-Compilation-20181109.pdf